Criteria for Non formulary Use
Tiotropium (Spiriva®)
VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel

The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient situation.

Patients with Chronic Obstructive Pulmonary Disease (COPD) and who are clinically stable and doing well on ipratropium, Combivent, and/or a long-acting beta agonist (LABA) should not be switched to tiotropium. Rather, tiotropium should be utilized in moderate to severe COPD patients who continue to have exacerbations on therapies mentioned above.

Criteria for use for tiotropium

The following 3 criteria must be met

- Diagnosis of COPD (FEV1/FVC < 70%, FEV1 < 65% of predicted value)*
- Combivent or ipratropium $\geq$ 2 puffs QID (+ albuterol, as needed and tolerated) for at least 3 months**
- $\geq$ 2 COPD exacerbations requiring urgent or emergent care or $\geq$ 1 exacerbation requiring hospitalization in the last year***

*Tiotropium should not be used for asthma

** Note that the above assumes that patients are able and willing to use inhalers properly; patients should initially be instructed on use of inhalers and their technique should be reassessed and/or observed if they have exacerbations or have suboptimal symptom control. Handihaler should not be used if the patient cannot use correctly.

***COPD exacerbation: a sustained worsening of the patient's condition, from the stable state and beyond normal day-to-day variations, necessitating a change in regular medication in a patient with underlying COPD (Chest 2000; 117:398S-401S).

1. Ipratropium or Combivent will automatically be discontinued once tiotropium is initiated. A short-acting beta-agonist should still be made available for "as needed" use.

2. Since formoterol is also a dry powder capsule, patients also using formoterol must be instructed to use the correct delivery device for the correct drug (formoterol with Aerolizer and tiotropium with Handihaler)

3. Patients on long-term oral steroids are eligible for tiotropium, provided they meet the first 2 criteria, even if clinically stable if the goal is to reduce or eliminate the oral steroid dose.

4. If symptoms improve with tiotropium, consider therapeutic trial of stopping the LABA, if applicable.

5. If symptoms DO NOT improve with tiotropium:

    - At the present time there is NO EVIDENCE that an increased dose over the initial recommended daily dose of 18mcg once daily is of any benefit
    - Consider changing to a LABA if not previously tried

6. If applicable, consider discontinuing inhaled corticosteroids if they have not yet improved symptomatology.

September 2004 – amended February 2005
Updated versions may be found at http://www.pbm.va.gov or http://vaww.pbm.va.gov

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